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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/868,123	04/02/2002	Mary Collins	22058-514NATL	5639

7590 11/07/2006

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EXAMINER	
DEBERRY, REGINA M	

ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 11/07/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/868,123	COLLINS ET AL.	
	Examiner	Art Unit	
	Regina M. DeBerry	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 August 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *23,28,48-53,55,59-62 and 64-67* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *23,28,48-53,55,59-62 and 64-67* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *8/06,10/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Status of Application, Amendments and/or Claims

The amendment filed 22 August 2006 has been entered in full. Claims 1-22, 24-27, 29-47, 54, 56-58 and 63 are cancelled. Claims 23, 28, 48-53, 55, 59-62, 64-67 are pending and under examination.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Information Disclosure Statement

The information disclosure statement(s)(IDS) filed 22 August 2006 was received and complies with the provisions of 37 CFR §§1.97 and 1.98. It has been placed in the application file and the information referred to therein has been considered as to the merits.

Withdrawn Objections And/Or Rejections

The rejection to claims 23, 28, 48-53, 55-57, 59-62 and 64-67 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement (new matter), as set forth at pages 3-4 of the previous Office Action (22 February 2006), is *withdrawn* in view of the amendment (22 August 2006).

The rejection to claims 23, 28, 48, 55, 57, 59, 64 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 6-8 and 14 of U.S. Patent No. 6,248,714 B1 in view of Cookson *et al.,* US 6,387,615 B2, as set forth

at pages 4-5 of the previous Office Action (22 February 2006), is *withdrawn* in view of the amendment (22 August 2006).

The rejection to claims 23, 28, 48-53, 55-57, 59-62, 64-67 under 35 U.S.C. 102(b) as being anticipated by Collins *et al.,* US Patent 5,710,023, as set forth at pages 5-6 of the previous Office Action (22 February 2006), is *withdrawn* in view of the amendment (22 August 2006).

The rejection to claims 23, 28, 48-53, 55-57, 59-62, 64-67 under 35 U.S.C. 102(e) as being anticipated by Collins *et al.,* US Patent 6,248,714 B1, as set forth at pages 6-7 of the previous Office Action (22 February 2006), is *withdrawn* in view of the amendment (22 August 2006).

The rejection to claims 23, 28, 48-53, 55-57, 59-62, 64-67 under 35 U.S.C. 102(e) as being anticipated by Collins *et al.,* US Patent 6,268,480 B1, as set forth at pages 7-8 of the previous Office Action (22 February 2006), is *withdrawn* in view of the amendment (22 August 2006).

The rejection to claims 23, 28, 48-53, 55-57, 59-62, 64-67 under 35 U.S.C. 102(e) as being anticipated by Collins *et al.,* US Patent 6,214,559 B1, as set forth at pages 8-9 of the previous Office Action (22 February 2006), is *withdrawn* in view of the amendment (22 August 2006).

Double Patenting

Claims 23, 28, 48, 55, 59 and 64 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 6-8 and 14 of

U.S. Patent No. 6,248,714 B1 in view of Cookson *et al.,* US 6,387,615 B2 (reference of record), Hamelmann *et al.* (Allergy and Clinical Immunology International, Abstract, Vol. 10/2:59-63, 1998) and King (Journal of the National Medical Association, Abstract, Vol. 91/8:9S-15S, August 1999).

Instant claims 23, 48, 55 and claim 1 of patent '714 are both drawn to a method of inhibiting binding of IL-13 to the IL-13 receptor in a mammalian subject comprising, administering a polypeptide comprising amino acids 26 to 341 of SEQ ID NO:4. Water is considered a pharmaceutically acceptable carrier. Claims 6-8 and 14 of patent '714 are drawn to a method of treating an Ig-mediated condition in a mammal comprising administering a protein comprising the amino acid sequence comprising 26 to 341 of SEQ ID NO:4. Instant claims 28, 59 and 64 are drawn to a method of treating an allergen-induced airway hyper responsiveness in a mammalian subject comprising administering a polypeptide comprising amino acids 26 to 341 of SEQ ID NO:4.

Cookson *et al.* teach that most asthma in children and young adults is initiated by IgE mediated allergy to inhaled allergens (column 1, lines 10-24 and lines 34-46). King teaches that asthma is characterized by hyper responsiveness and airway obstruction and that allergens can induce asthma. Hamelmann *et al.* teach experiments directed at treating airway hyper responsiveness (AHR) in bronchial asthma. Thus, allergen-induced airway hyper responsiveness is an IgE mediated condition. Asthma is characterized by hyper responsiveness and airway obstruction.

Although the conflicting claims are not identical, they are not patentably distinct from each other. Both sets of claims teach a method of inhibiting IL-13 to the IL-13

receptor in a mammalian subject comprising administering a polypeptide comprising amino acid residues 26 to 341 of SEQ ID NO:4. It would be obvious to modify the method of treating an IgE mediated condition comprising administering IL-13bc as claimed in patent '714 to treat allergen-induced airway hyper responsiveness in a mammalian subject with a reasonable expectation of success. Cookson *et al.* teach that most asthma in children and young adults is initiated by IgE mediated allergy to inhaled allergens. King and Hamelmann teach that asthma is characterized by hyper responsiveness and airway obstruction and that allergens can induce asthma. Since asthma is an IgE mediated condition characterized by hyper responsiveness, airway obstruction and allergens, it would be obvious to use the method of the instant patent to treat hyper responsiveness.

Claim Rejections - 35 U.S.C. § 103(a)

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was

not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 23, 28, 48-53, 55, 59-62, 64-67 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Collins *et al.*, US Patent 5,710,023** (reference of record) in view of Hamelmann *et al.* (Allergy and Clinical Immunology International, Abstract, Vol. 10/2:59-63, 1998) and King (Journal of the National Medical Association, Abstract, Vol. 91/8:9S-15S, August 1999).

Collins *et al.* teach the human cDNA of IL-13 binding chain (bc) as SEQ ID NO:3 and the human polypeptide of IL-13bc as SEQ ID NO:4 (column 3, line 60-column 4, line 28). Collins *et al.* teach pharmaceutical compositions comprising a fusion protein. The fusion protein comprises amino acids 26 to 341 of SEQ ID NO:4 and an Fc fragment (column 2, lines 22-42 and column 3, lines 1-15). Collins *et al.* teach methods of inhibiting binding of IL-13 to the IL-13 receptor in a mammalian subject comprising administering a therapeutically effective amount of a composition comprising IL-13bc (column 3, lines 39-45). Collins *et al.* teach the administration of IL-13bc for the treatment of asthma (column 8, lines 1-10).

Collins *et al.* do not teach a method of treating allergen-induced airway hyper responsiveness comprising administering SEQ ID NO:4. King teaches that asthma is characterized by hyper responsiveness and airway obstruction and that allergens can induce asthma. Hamelmann *et al.* teach experiments directed at treating airway hyper responsiveness (AHR) in bronchial asthma.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify a method of treating asthma by administering IL-13bc as taught by Collins *et al.* to treat allergen-induced airway hyper responsiveness with a reasonable expectation of success. The motivation and expected success is provided by Collins, King and Hamelmann. Collins *et al.* teach a mechanism for inhibiting the binding of IL-13 to the IL-13 receptor in a mammalian subject comprising administering a therapeutically effective amount of a composition comprising IL-13bc. Collins *et al.* teach that the method can be used in the treatment of asthma. King and Hamelmann teach that asthma is characterized by hyper responsiveness and airway obstruction and that allergens can induce asthma. Since asthma is characterized by hyper responsiveness, airway obstruction and allergens, it would be obvious to use the method of Collins *et al.* to treat hyper responsiveness.

Claims 23, 28, 48-53, 55, 59-62, 64-67 are rejected under 35 U.S.C. 103(a) as being obvious over **Collins *et al.*, US Patent 6,248,714 B1** in view of Hamelmann *et al.* (Allergy and Clinical Immunology International, Abstract, Vol. 10/2:59-63, 1998) and King (Journal of the National Medical Association, Abstract, Vol. 91/8:9S-15S, August 1999).

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome

by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(l)(1) and § 706.02(l)(2).

Collins *et al.* teach SEQ ID NO:3 as human cDNA of IL-13bc and SEQ ID NO:4 as the human polypeptide of IL-13 bc (column 4, lines 1-28). Collins *et al.* teach pharmaceutical compositions comprising a fusion protein. The fusion protein comprises amino acids 26 to 341 of SEQ ID NO:4 and an Fc fragment (column 2, lines 30-49 and column 3, lines 1-22). Collins *et al.* teach methods of inhibiting binding of IL-13 to IL-13 receptor in a mammalian subject comprising administering a therapeutically effective amount of a composition comprising IL-13bc (column 3, lines 45-50 and claims). Collins *et al.* teach the administration of IL-13bc for the treatment of asthma (column 8, lines 7-20 and claims).

Collins *et al.* do not teach a method of treating allergen-induced airway hyper responsiveness comprising administering SEQ ID NO:4. King teaches that asthma is

characterized by hyper responsiveness and airway obstruction and that allergens can induce asthma. Hamelmann *et al.* teach experiments directed at treating airway hyper responsiveness (AHR) in bronchial asthma.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify a method of treating asthma by administering IL-13bc as taught by Collins *et al.* to treat allergen-induced airway hyper responsiveness with a reasonable expectation of success. The motivation and expected success is provided by Collins, King and Hamelmann. Collins *et al.* teach a mechanism for inhibiting the binding of IL-13 to the IL-13 receptor in a mammalian subject comprising administering a therapeutically effective amount of a composition comprising IL-13bc. Collins *et al.* teach that the method can be used in the treatment of asthma. King and Hamelmann teach that asthma is characterized by hyper responsiveness and airway obstruction and that allergens can induce asthma. Since asthma is characterized by hyper responsiveness, airway obstruction and allergens, it would be obvious to use the method of Collins *et al.* to treat hyper responsiveness.

Claims 23, 28, 48-53, 55, 59-62, 64-67 are rejected under 35 U.S.C. 103(a) as being obvious over **Collins *et al.*, US Patent 6,268,480 B1** in view of Hamelmann *et al.* (Allergy and Clinical Immunology International, Abstract, Vol. 10/2:59-63, 1998) and King (Journal of the National Medical Association, Abstract, Vol. 91/8:9S-15S, August 1999).

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(l)(1) and § 706.02(l)(2).

Collins *et al.* teach SEQ ID NO:3 as human cDNA of IL-13bc and SEQ ID NO:4 as the human polypeptide of IL-13bc (column 4, lines 1-30). Collins *et al.* teach pharmaceutical compositions comprising a fusion protein. The fusion protein comprises amino acids 26 to 341 of SEQ ID NO:4 and an Fc fragment (column 2, lines 30-65; column 3, lines 1-22 and claims). Collins *et al.* teach methods of inhibiting binding of IL-13 to IL-13 receptor in a mammalian subject comprising administering a therapeutically effective amount of a composition comprising IL-13bc (column 3, lines 45-50). Collins *et*

al. teach the administration of IL-13bc for the treatment of asthma (column 8, lines 7-20).

Collins *et al.* do not teach a method of treating allergen-induced airway hyper responsiveness comprising administering SEQ ID NO:4. King teaches that asthma is characterized by hyper responsiveness and airway obstruction and that allergens can induce asthma. Hamelmann *et al.* teach experiments directed at treating airway hyper responsiveness (AHR) in bronchial asthma.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify a method of treating asthma by administering IL-13bc as taught by Collins *et al.* to treat allergen-induced airway hyper responsiveness with a reasonable expectation of success. The motivation and expected success is provided by Collins, King and Hamelmann. Collins *et al.* teach a mechanism for inhibiting the binding of IL-13 to the IL-13 receptor in a mammalian subject comprising administering a therapeutically effective amount of a composition comprising IL-13bc. Collins *et al.* teach that the method can be used in the treatment of asthma. King and Hamelmann teach that asthma is characterized by hyper responsiveness and airway obstruction and that allergens can induce asthma. Since asthma is characterized by hyper responsiveness, airway obstruction and allergens, it would be obvious to use the method of Collins *et al.* to treat hyper responsiveness.

Claims 23, 28, 48-53, 55, 59-62, 64-67 are rejected under 35 U.S.C. 103(a) as being obvious over Collins ***et al.,*** **US Patent 6,214,559 B1** in view of Hamelmann *et al.*

(Allergy and Clinical Immunology International, Abstract, Vol. 10/2:59-63, 1998) and King (Journal of the National Medical Association, Abstract, Vol. 91/8:9S-15S, August 1999).

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Collins *et al.* teach SEQ ID NO:3 as the human cDNA of IL-13 binding chain of IL-13 receptor and SEQ ID NO:4 as the human protein of IL-13 binding chain of IL-13 receptor (column 4, lines 16-30). Collins *et al.* teach pharmaceutical compositions comprising a fusion protein, amino acids 26 to 341 of SEQ ID NO:4 and an Fc fragment (column 2, lines 30-65; column 3, lines 1-22). Collins *et al.* teach methods of inhibiting binding of IL-13 to IL-13 receptor in a mammalian subject comprising administering a therapeutically effective amount of a composition comprising IL-13bc (column 3, lines 45-50). Collins *et al.* teach the administration of IL-13bc for the treatment of asthma (column 8, lines 7-20).

Collins *et al.* do not teach a method of treating allergen-induced airway hyper responsiveness comprising administering SEQ ID NO:4. King teaches that asthma is characterized by hyper responsiveness and airway obstruction and that allergens can

induce asthma. Hamelmann *et al.* teach experiments directed at treating airway hyper responsiveness (AHR) in bronchial asthma.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify a method of treating asthma by administering IL-13bc as taught by Collins *et al.* to treat allergen-induced airway hyper responsiveness with a reasonable expectation of success. The motivation and expected success is provided by Collins, King and Hamelmann. Collins *et al.* teach a mechanism for inhibiting the binding of IL-13 to the IL-13 receptor in a mammalian subject comprising administering a therapeutically effective amount of a composition comprising IL-13bc. Collins *et al.* teach that the method can be used in the treatment of asthma. King and Hamelmann teach that asthma is characterized by hyper responsiveness and airway obstruction and that allergens can induce asthma. Since asthma is characterized by hyper responsiveness, airway obstruction and allergens, it would be obvious to use the method of Collins *et al.* to treat hyper responsiveness.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a). A shortened statutory period for reply to this final action is set to expire

THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Regina M. DeBerry whose telephone number is (571) 272-0882. The examiner can normally be reached on 9:00 a.m.-6:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda G. Brumback can be reached on (571) 272-0961. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

RMD
11/1/06

Marianne P. Allen

MARIANNE P. ALLEN
PRIMARY EXAMINER

11/2/06

AU 1647